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- 16. (Amended) Method according to claim 3, wherein the tubular reactors are arranged essentially vertically when in operation and product to be hydrolyzed is conveyed from the bottom to the top.
- 20. (Amended) Method according to claim 1, wherein main hydrolysis is carried out in the tubular tempered reactor for up to 60-90%.

Marked up versions of the above amended claims are attached hereto.

#### **REMARKS**

Minor corrections have been made in the Specification and an Abstract has been provided.

No new matter has been added.

Claims 1-20 remain in the application. Reexamination and reconsideration of the application, as amended, are requested.

Claim 12 was objected to due to the misspelling of the word "least", and claim 12 has been amended to overcome this objection.

Claim 10 was rejected under 35 U.S.C. 101 as being an improper definition of a process.

Claim 1 has been amended to set forth the steps involved in the process.

Claims 1-20 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Regarding claim 1, the phrase "possibly substituted" has been amended to "optionally substituted". Further in claim 1, the word "converting" has been changed to "hydrolyzing". Please consider that a high molecular weight starch is "converted" to starch having a lower molecular weight. The term "reaction stage" has been amended to "reactor". The term "essentially free of mixing" means to preclude mechanical mixing or mixing due to turbulent flow. In consideration of the invention, a mixing of the solution or the suspension has to be avoided. Please consider that in prior art, hydrolysis mixing is desired. Means to achieve such mixing are well known in the art. In contrast thereto, the present hydrolysis avoids such mixing. Therefore, not only mechanical mixing

is precluded, but also other means to achieve a turbulent flow. Such means are well known in the art. Therefore, it is believed that the present expression is clear.

Regarding the term "fine hydrolysis" in claims 3 and 14, please consider the disclosure on page 5, last paragraph. It is clear that a "fine hydrolysis" is an optional second hydrolysis (see page 2, 2<sup>nd</sup> paragraph). The second step enables a "fine" adjustment to a desired molecular weight of the starch. It should be clear that the "fine" or "rough" hydrolysis is based on the molecular weight. Please consider that the mandatory "rough" hydrolysis may lead to a product having a molecular weight within some limits. To improve the accuracy of the molecular weight, a second hydrolysis step may be performed. In consideration of the specification, the terms should be clear to a person skilled in the art.

Regarding the clarity of the term "hydrolysis is carried out ... for up to 60 to 90%" in claims 6 and 20, please consider that a person skilled in the art knows about the molecular weight of the starting product. Furthermore, the person knows about the desired molecular weight of the end product. The desired degradation can be defined as 100%. As mentioned above, it is somewhat difficult to achieve a very exact molecular weight by using the hydrolysis process according to claim 1. However, a second conventional hydrolysis step may be performed. In consideration of these statements, the term "hydrolysis is carried out ... for up to 60 to 90%" should be clear.

The "mixing elements" of claims 3, 18 and 14 do not render these claims indefinite. Regarding the fine hydrolysis, such second step hydrolysis is performed in a conventional way. That is, the second step hydrolysis is performed by using a conventional mixer. Therefore, the restriction does not contravene against the teaching of present claim 1.

Regarding present claim 9, a partially broken down starch is used as a starting material (see page 7, last paragraph). Therefore, the claim should be clear.

In claim 11, it should be clear that a conventional pump can be used. The terms "arrangement" and the conduit element have been deleted to clarify the claim.

The claims have also been amended to provide antecedent basis where required.

Claims 1-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sommermeyer in combination with Komai. Claim 1 has been amended to restrict the present claims to a

degradation of a starch <u>solution</u> and the term "suspension" has been cancelled. The teaching of Komai concerns the saccharification of starch. Thus, starch is degraded to sugar monomers or oligomers. Please see the figures 4 and 5 of the '664 specification. It should be clear that the molecular weight distribution of these compounds does not matter, because the starch is degraded to very low molecular weight products. Nevertheless, figure 5 suggests a very wide distribution, although the starch is degraded to such monomers. This wide distribution is due to the use of starch slurry.

In contrast, the present invention provides a method to degrade starch to a desired molecular weight having a small molecular weight distribution. Such improvement is due to the use of a starch solution. Please consider that Komai does not give any hint that a starch can be degraded to a desired molecular weight polymer having a small molecular weight distribution. Please consider that a small distribution of the molecular weight is necessary to use the starch as a plasma expender. It is absolutely astonishing that such small distribution can be achieved by using a starch solution instead of a starch slurry.

Furthermore, the present invention provides a method by which a desired molecular weight can be achieved. In contrast, '664 describes only a method for the saccharification of starch. Especially figure 5 suggests that a high amount of sugar monomers and oligomers are produced at low degrees of hydrolysis. Therefore, Komai teaches away from the present invention. A combination of Sommermeyer and Komai can only be realized in the knowledge of the present invention. Consequently, such combination is achieved with the benefit of hindsight.

No additional claim fee is required by this Amendment.

In view of the above, it is believed that all remaining claims are now in condition for allowance and such favorable action is earnestly solicited.

Respectfully submitted,

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#### MARKED UP VERSION SHOWING CHANGES MADE

#### IN THE SPECIFICATION:

On page 3, first paragraph, line 1, delete "claim 1" and insert the present invention therefor.

On page 3, first paragraph, line 3, delete "in claims 2 to 9".

Please substitute the following first paragraph, which incorporates the above amendments for the pending first paragraph:

This object is solved by a method according to [claim 1] the present invention. Further advantageous embodiments of the method according to the invention are described [in claims 2 to 9].

On page 3, second paragraph, line 2, delete "as per claims 1 to 9".

On page 3, second paragraph, line 6, delete "according to claims 11 to 13".

Please substitute the following second paragraph, which incorporates the above amendments for the pending second paragraph:

A further object of the invention is the use of the products produced according to a method [as per claims 1 to 9] as a plasma diluent or to produce dialysis solutions. A further object of the invention is a device for carrying out a method for the continuous production of hydrolytically broken down starch derivatives [according to claims 11 to 13].

On page 3, after the second paragraph, please insert the following:

### Brief Description of the Drawings

FIG. 1 is a schematic diagram illustrating the device for the continuous hydrolysis of starch or starch derivatives.

#### Kindly insert the following for the Abstract:

#### -- Abstract of the Disclosure

The invention relates to a method for the continuous production of hydrolytically broken down starch or hydrolytically broken down substituted starch products such as hydroxyethyl- or hydroxypropyl starch. The invention essentially consists of carrying out most of the hydrolytic breakdown in a pipe-shaped, temperature-controlled reactor having no mixing elements. The remaining breakdown is carried out in one or more reactors fitted with mixing elements (fine hydrolysis). The product obtained can be used both in the food industry and for medical purposes, especially as plasma diluent.--

#### IN THE CLAIMS:

PLEASE SUBSTITUTE THE FOLLOWING CLAIMS 1, 3, 4, 5, 6, 7, 10, 11, 12, 15, 16, AND 20 FOR THE PENDING CLAIMS 1, 3, 4, 5, 6, 7, 10, 11, 12, 15, 16, AND 20:

1. (Twice Amended) Method for the continuous production of hydrolytically broken down starch derivatives that are [possibly] optionally substituted, by [converting] hydrolyzing with a hydrolysis agent in an aqueous medium and subsequent neutralization to stop the hydrolysis, wherein a solution [or suspension] that contains the starch or [possibly] optionally substituted starch to be hydrolyzed is continuously conveyed through a reactor [reaction stage] essentially free of mixing against the force of gravity in the hydrolysis step.



3. (Twice Amended) Method according to claim 1, wherein a fine hydrolysis is carried out after [the] a main hydrolysis, [the] a roughly hydrolyzed starch solution being fed to a tubular reactor with mixing elements at a preset temperature during said fine hydrolysis.

- 4. (Twice Amended) Method according to claim 1, wherein [the] tubular reactors are arranged essentially vertically when in operation and [that the] product to be hydrolyzed is conveyed from the bottom to the top.
- 5. (Twice Amended) Method according to claim 1, wherein [the] tubular reactors are tempered at a preset temperature of 25 to 100°C.



- 6. (Twice Amended) Method according to claim 1, wherein [the] main hydrolysis is carried out in [the] a tubular tempered reactor for up to 60-90%.
- 7. (Twice Amended) Method according to claim 1, wherein etherified starch, [preferably] including a starch etherified with at least one of ethylene oxide and propyl oxide, optionally a wax corn starch, is used.
- 10. (Twice Amended) [Use of the hydrolytically broken down product produced according to claim 1 as] A method of producing a plasma diluent or [for the production of] dialysis solutions comprising the step of providing hydrolytically broken down starch derivatives that are optionally substituted, by hydrolyzing with a hydrolysis agent in an aqueous medium and subsequent neutralization to stop the hydrolysis, wherein a solution that contains the starch or optionally substituted starch to be hydrolyzed is continuously conveyed through a reactor essentially free of mixing against the force of gravity in the hydrolysis step.



11. (TwiceAmended) Device for carrying out the method according to claim 1 including a feeding device for starch solution, a container for a hydrolyzing agent, a mixing and heating station for mixing the starch solution with the hydrolyzing agent and heating the mixture to a preset temperature, and a pump [arrangement] for feeding the mixture into at least one reactor[, a conduit that connects all units with one another as well as a neutralization station for neutralizing the mixture],

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whereby the reactor, when in use, is arranged essentially vertically and has an inlet tube at the bottom and an outlet tube at the top and the pump [arrangement] is operated in such a way that it continuously feeds the starch solution to the inlet tube at the bottom at a preset pump rate, so that the starch solution is conveyed through the reactor to the outlet tube against the force of gravity.

- 12. (Twice Amended) Device according to claim 11, wherein a fine hydrolysis station in the form of at [lest] <u>least</u> one reactor unit is connected in tandem after the reactor as a main hydrolysis station, each of said reactor units having mixing elements.
- 15. (Amended) Method according to claim 2, wherein the tubular reactors are arranged essentially vertically when in operation and [that the] product to be hydrolyzed is conveyed from the bottom to the top.
- 16. (Amended) Method according to claim 3, wherein the tubular reactors are arranged essentially vertically when in operation and [that the] product to be hydrolyzed is conveyed from the bottom to the top.



20. (Amended) Method according to claim 1, wherein [the] main hydrolysis is carried out in the tubular tempered reactor for up to 60-90%.